Draft Guidance for Industry and FDA Staff

Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions

DRAFT GUIDANCE

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For questions regarding this draft guidance, contact the Center for Tobacco Products (CTP) at 1-877-CTP-1373.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

Preface

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

This draft guidance provides information in response to frequently asked questions that the Center for Tobacco Products (CTP or we) is receiving from manufacturers and other interested stakeholders (you) on demonstrating the substantial equivalence of a new tobacco product.

- In general, a tobacco product manufacturer must submit a premarket application and obtain a marketing authorization order before the manufacturer may introduce a new tobacco product into interstate commerce (section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act); 21 U.S.C. 387j).
- A premarket application and a marketing authorization order under section 910(c)(1)(A)(i) is not required, however, if a manufacturer submits a substantial equivalence report under section 905(j) and obtains an order under section 910(a)(2). The report must include information demonstrating that the tobacco product is (1) substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007, (2) in compliance with the requirements of the FD&C Act, including compliance with registration, listing, and tobacco product standard requirements, and (3) in compliance with section 907 (section 905(j)(1)(A)(i), (B)) of the FD&C Act.

FDA previously issued a guidance, "*Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products*," that includes recommendations on the content of section 905(j) (substantial equivalence) reports and FDA's review of 905(j) reports.[1]

- An order under 910(c)(1)(A)(i) is also not required for a new tobacco product if the tobacco product has been modified by adding or deleting a tobacco additive or increasing or decreasing the quantity of an existing tobacco additive, the manufacturer has submitted an exemption request under section 905(j)(3), and if FDA grants the exemption request after determining that (1) the modification is a minor modification of a tobacco product that can be sold under the FD&C Act, (2) a report demonstrating substantial equivalence is not necessary to ensure that permitting the product to be marketed would be appropriate for protection of the public health, and (3) an exemption is otherwise appropriate.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Responses to Frequently Asked Questions

This section provides our responses to questions that you have asked us on the substantial equivalence provisions. We have used the exact question that was submitted to CTP except to modify or add language when needed to clarify the question**.**

In addition, many of the questions use the term "new tobacco product." Rather than repeat the definition in every response, we are providing the definition here, and you should refer back to it as necessary.

A "new tobacco product" means:

1. any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or
2. any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

(Section 910(a) of the FD&C Act; 21 U.S.C. 387j(a).)

[1] The *Guidance for Industry and FDA Staff: Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products* may be accessed at http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM239021.pdf.

"Tobacco product" is defined as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)" (section 201 of the FD&C Act; 21 U.S.C. 321). The label and packaging is part of a tobacco product.

We also note that some of the questions and answers refer to the pathways to market and generally identify two pathways to market: a substantial equivalence report intended to demonstrate substantial equivalence to a predicate product or a pre-market tobacco application. A third pathway to market would be a request for an exemption from the substantial equivalence requirements under section 905(j)(3) and a subsequent report under section 905(j)(1)(A)(ii). As described above, the exemption pathway applies to tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing additive, if FDA determines the modification is a minor modification of a tobacco product that can be sold under the Act, a report demonstrating substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health, and an exemption is otherwise appropriate. CTP has issued a rule that establishes the procedures for making an exemption request (76 Federal Register 38961, July 5, 2011). If FDA grants an exemption from the substantial equivalence requirements, manufacturers must only submit a report under section 905(j)(1)(A)(ii) stating (1) the tobacco product is modified within the meaning of the exemptions provision, (2) the modifications are to a product that is commercially marketed and in compliance with the requirements of the FD&C Act, (3) all of the modifications are covered by exemptions granted under section 905(j)(3) of the FD&C Act, and (4) actions taken to ensure that the tobacco product is in compliance with section 907.

These answers are specific to premarket requirements of the FD&C Act and are not intended to speak to any other requirements of the FD&C Act. Manufacturers are encouraged to review the FD&C Act, the regulations in effect, and any available guidances.

A. LABELS and PACKAGING

The label and packaging of a tobacco product is considered a "part" of that product. A change to any part of a tobacco product after February 15, 2007 makes that product a "new tobacco product." As discussed in greater detail below, however, the agency does not intend to enforce the requirements of sections 905(j) and 910 of the FD&C Act for the following four limited modifications to labels and packaging:

1. Question:
Would a cigarette be a "new tobacco product," and subject to the substantial equivalence provisions of the FD&C Act, if the cigarette was marketed on February 15, 2007, but the descriptors (*e.g.*, "light," "mild" or "low") were subsequently eliminated from the packaging or label in compliance with the new tobacco law?

Response:

If the tobacco product was commercially marketed in the United States on February 15, 2007, and no other modifications occurred to the tobacco product after February 15, 2007, we do not intend to enforce the premarket requirements of sections 905(j) and 910 of the FD&C Act for modifications to product packaging or labels to remove the descriptors 'light', 'mild', or 'low' or similar descriptors to comply with section 911 of the FD&C Act (21 U.S.C. 387k).

2. Question:
Would a cigarette be a "new tobacco product," and subject to the substantial equivalence provisions of the FD&C Act, if the cigarette was marketed on February 15, 2007, but the graphic warnings are subsequently added in compliance with the new tobacco law (see section 201 of the Tobacco Control Act)?

Response:

The final rule implementing the requirements to display color graphics depicting the negative health consequences of smoking published on June 22, 2011 (see 76 Federal Register 36628, June 22, 2011). This rule will become effective September 22, 2012. We do not intend to enforce the premarket requirements of sections 905(j) and 910 of the FD&C Act for a tobacco product that was commercially marketed in the United States on February 15, 2007, and that had no modifications after February 15, 2007, other than to comply with the graphic warning requirements of section 201 when in effect.

3. Question:
Would a cigarette be a "new tobacco product," and subject to the substantial equivalence provisions of the FD&C Act, if the cigarette was marketed on February 15, 2007, but the cigarette package was subsequently changed from soft pack to hard pack (or from hard pack to soft pack)?

Response:

If the tobacco product was commercially marketed in the United States on February 15, 2007, the package was changed from a soft pack to a hard pack (or from a hard pack to a soft pack) after February 15, 2007, and this change did not modify the tobacco product in any other way (e.g., a change in moisture content, shelf life, ingredient composition, nicotine delivery, harmful/potentially harmful constituents), and no other modifications were made to the tobacco product after February 15, 2007, then we do not intend to enforce the premarket requirements of sections 905(j) and 910 for this type of modification. However, if the change from a soft pack to a hard pack (or from a hard pack to a soft pack) modified the tobacco product in any other way, we intend to enforce the premarket requirements of sections 905(j) and 910, and manufacturers of such products must follow a regulatory pathway to market (i.e., a substantial equivalence

report under 905(j)(1), or a pre-market tobacco application under 910(b)). (Section 910(a)(2) of the FD&C Act.)

4. Question:
Would a cigarette be a "new tobacco product," and subject to the substantial equivalence provisions of the FD&C Act, if the cigarette was marketed on February 15, 2007, but subsequently a change to font size, ink color, or background color was made to the packaging or labels?

Response:

If the tobacco product was commercially marketed in the United States on February 15, 2007, but a modification to font size, ink color, or background color was made to the packaging or labels after February 15, 2007 and no other modifications were made to the tobacco product after February 15, 2007, then we do not intend to enforce the premarket requirements of sections 905(j) and 910 of the FD&C Act for this type of modification, provided the modification does not raise different questions of public health (section 910(a)(2); 21 U.S.C. 387j(a)(2)), and you are in compliance with all other statutory labeling and packaging requirements of the Tobacco Control Act (e.g., Sections 201 and 204 of the Tobacco Control Act).

If a modification to the font size, ink color, or background color of a tobacco product's packaging raises different questions of public health, then we intend to enforce the premarket requirements under sections 905(j) and 910 of the FD&C Act for the product.

If you have additional questions regarding changes to font size, ink color, or background color and the need for submission of 905(j) reports, and would like to discuss your questions with the agency, please contact CTP to request a meeting in accordance with 21 C.F.R. 10.65.[2]

B. PRODUCT NAMES/LINE EXTENSIONS

5. Question:
Would a cigarette be a "new tobacco product," and subject to the substantial equivalence provisions of the FD&C Act, if the cigarette was marketed on February 15, 2007, but subsequently the name of the product was modified or changed?

Response:

[2] You may contact CTP at 1-877-CTP-1373 or CTP, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, Maryland, 20850-3229.

Yes. If the cigarette was marketed on February 15, 2007, but subsequently the name of the cigarette brand was modified or changed, the cigarette is a new tobacco product and subject to the premarket requirements of sections 905(j) and 910. Thus, the manufacturer must follow an appropriate regulatory pathway to market (i.e., a substantial equivalence report under 905(j), or a pre-market tobacco application under 910(b)). (Section 910(a)(2) of the FD&C Act.)

6. Question:
If a manufacturer markets a cigarette as "Brand X" on February 15, 2007, and, after that date, continues to market Brand X but also begins to market the identical cigarette under the additional name "Brand Y," would "Brand Y" be a "new tobacco product," and subject to the substantial equivalence provisions?

Response:

Yes. "Brand Y" is a new tobacco product subject to the premarket requirements of sections 905(j) and 910, and the manufacturer must follow one of the regulatory pathways for legal marketing in the United States, i.e., submission of a substantial equivalence report under 905(j), or a pre-market tobacco application under 910(b).

C. ADDITIVES/SPECIFICATIONS

7. Question:
Would a cigarette be a "new tobacco product," and subject to the substantial equivalence provisions, if the cigarette was marketed on February 15, 2007, but subsequently a new supplier was used for an additive, but the specification of the additive remains unchanged?

Response:

If the tobacco product was commercially marketed in the United States on February 15, 2007, and subsequently a new supplier is used for the same additive with identical specifications, and this does not result in a change in any component, part, constituent, additives, or ingredient in the tobacco product, then this type of change would not render the product a new tobacco product. Please note, however, if a new supplier either uses a different additive, or the same additive but changing the supplier results in a change in any component, part, constituent, additives, or ingredient in the tobacco product, then we intend to enforce the premarket requirements of sections 905(j) and 910, and the manufacturer must follow a regulatory pathway to market (i.e., a substantial equivalence report under 905(j), a pre-market tobacco application under 910(b), or an exemption from the substantial equivalence requirements under 905(j)(3)). (Section 910(a)(2) of the FD&C Act.)

8. Question: Would a tobacco product be a "new tobacco product," and subject to the substantial equivalence provisions if a tobacco blending change is made to address variation in tobacco growing conditions?

Response:

At this time, FDA does not intend to enforce the requirements of sections 910 and 905(j) for tobacco blending changes required to address the natural variation of tobacco (e.g., tobacco blending changes due to variation in growing conditions) in order to maintain a consistent product. Tobacco blending changes that are intended to alter the chemical or perception properties of the new product (e.g., nicotine level, pH, smoothness, harshness, etc.) compared to the predicate should be reported in a premarket application under section 910 and 905(j) of the FD&C Act. If you have any questions regarding whether a specific tobacco blending change you have made will be subject to the requirements of sections 910 and 905(j) of the FD&C Act, please contact us (see also the *Guidance for Industry and FDA Staff: Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products*).

9. Question:
Would a cigarette be a "new tobacco product," and subject to the substantial equivalence provisions, if the cigarette was marketed on February 15, 2007, but subsequently a specification for an additive was tightened (i.e., narrowed) within the range of the original specification or the specification for an additive was changed, for example, from .003 to .005?

Response:

Any modification made to the level of an additive in a product after February 15, 2007 renders the product a new tobacco product, subject to one of the pathways for legal marketing in the United States, i.e., submission of a substantial equivalence report under 905(j), a pre-market tobacco application under 910(b), or an exemption from the substantial equivalence requirements under 905(j)(3). Changes in controls on production, such as improved quality control, which do not affect the actual level of an additive in a product would not make that product a "new tobacco product" under the FD&C Act.

10. Question:
Would a cigarette be a "new tobacco product," and subject to the substantial equivalence provisions, if the cigarette was marketed on February 15, 2007, but subsequently the paper was changed to Fire-Safe Compliant ("FSC") paper?

Response:

A modification made to the cigarette paper to Fire-Safe Compliant ("FSC") paper after February 15, 2007 renders the product a new tobacco product, subject to one of the

regulatory pathways for legal marketing (i.e., submission of a substantial equivalence report under 905(j), a pre-market tobacco application under 910(b), or an exemption from the substantial equivalence requirements under 905(j)(3). (Section 910(a)(2).)

11. Question:
Would a cigarette be a "new tobacco product," and subject to the substantial equivalence provisions, if the cigarette was marketed on February 15, 2007, but subsequently a supplier of a component (e.g., the filter) began using a new processing aid (e.g., an antimicrobial agent) for a sub-component (e.g., paper used for the filter's plug wrap) and the change is so minor that it is not even capable of being quantified in the finished product?

Response:

This type of change may have an impact on other characteristics within the tobacco product (e.g., may alter chemical reactions and create a new ingredient, additive, or constituent). Therefore this change fits the definition of a modification under section 910(a)(1)(B) of the FD&C Act and renders the product a new tobacco product. The new tobacco product will be subject to one of the regulatory pathways for legal marketing (i.e., submission of a substantial equivalence report under 905(j), a pre-market tobacco application under 910(b), or an exemption from the substantial equivalence requirements under 905(j)(3)).

D. GENERAL QUESTIONS ABOUT 905(j) REPORTS

12. Question:
Would FDA be willing to create a mechanism whereby companies can contact the agency to determine if certain modifications convert an existing product into a "new tobacco product" and require a substantial equivalence filing?

Response:

If you have questions regarding certain changes and the need for submission of 905(j) reports, and would like to discuss your questions with the agency, please contact CTP to request a meeting in accordance with 21 C.F.R. 10.65.

In general, please be aware that for any tobacco product that was commercially marketed in the United States on February 15, 2007, any change to the product after February 15, 2007 would make the product a new tobacco product subject to one of the pathways for legal marketing in the United States, i.e., submission of a substantial equivalence report under 905(j), a pre-market tobacco application under 910(b), or an exemption from the substantial equivalence requirements under 905(j)(3). As noted in the January 5, 2011, *Guidance for Industry and FDA Staff: Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products,* we intend to allow manufacturers who have acted diligently in preparing their submissions a reasonable amount of time to supplement their

submissions provided these manufacturers submit a 905(j) report by the statutory deadline. FDA intends to determine what constitutes a reasonable period of time on a case-by-case basis.

13. Question:
When providing information on amounts and levels of additives, can companies round decimal points to the nearest hundredth? If not, how specific do companies need to be?

Response:

It is the applicant's/manufacturer's responsibility to present the data in a form that will provide the basis for FDA to determine if the new tobacco product is or is not substantially equivalent to the predicate product (as described in the *Guidance for Industry and FDA Staff: Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products).*

14. Question:
If a company currently markets the exact same cigarette (e.g., identical composition, specifications, design features) under multiple product names, can the company make one substantial equivalence submission covering all of the products, where it: (a) includes only one list of ingredients, specifications, design features, etc.; (b) identifies all of the products that list covers; and then (c) compares that one list to a list for a predicate product?

Response:

To avoid submitting identical 905(j) reports, manufacturers may submit one substantial equivalence report for all identical products that have different names. The manufacturer should determine how to structure the substantial equivalence report in order to accurately compare each new tobacco product to an appropriate predicate product. The cover letter should identify all products covered in the submission, both the new tobacco products and the predicate tobacco product to which they are being compared (see, e.g., section "V.A. Content/Data to Submit, Cover Letter" of the *Guidance for Industry and FDA Staff: Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products).*

15. Question:
How do I know whether a characteristic should be reported as a material or ingredient?

Response:

The statute defines "substantial equivalence" in terms of characteristics (section 910(a)(3)(A) of the FD&C Act). The statute also defines "characteristics" as the materials, ingredients, design, composition, heating source, or other features of a tobacco product (section 910(a)(3)(B) of the FD&C Act). However, the statute does not further define each of the terms used in the definition of "characteristics." The *Guidance for*

Industry and FDA Staff: Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products provides recommendations related to characteristics. In general, in preparing your substantial equivalence report, it is important that your comparison to a predicate be inclusive of all characteristics. We recognize that you may be uncertain of which category a particular characteristic best fits. For purposes of comparison, it is important that characteristics be reported in the same category for the new tobacco product and the predicate. FDA will review your submission as a whole and consider the totality of the data presented when making FDA's determination of substantial equivalence.

16. Question:
Glue is not listed as an example of a component, part, or accessory of a tobacco product in the *Guidance for Industry and FDA Staff: Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products*. Is glue considered a new tobacco product that might be subject to the substantial equivalence provisions?

Response:

For purposes of substantial equivalence, the characteristics of the new tobacco product should be compared to the characteristics of the appropriate predicate. Characteristics means the materials, ingredients, design, composition, heating source, or other features of the tobacco product. If the glue is modified in a tobacco product after February 15, 2007, the finished product is a new tobacco product and is subject to one of the pathways for legal marketing in the United States; e.g., a substantial equivalence report or a pre-market tobacco. However, as discussed in more detail in the January 5, 2011, *Guidance for Industry and FDA Staff: Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products*, FDA intends to limit its enforcement of the requirements of sections 910 and 905(j) to finished, regulated products. To avoid the submission of duplicative information, FDA does not at this time intend to enforce the requirements of 910 and 905(j) for components of regulated tobacco products that are sold or distributed solely for further manufacturing into finished tobacco products.

17. Question:
How should harmful and potentially harmful constituents (HPHC) be reported in my 905(j) report?

Response:

We recommend that you provide information regarding HPHC as appropriate to demonstrate that the new tobacco product is substantially equivalent to the predicate product. Thus, you should provide any information on HPHC that would be appropriate to show that the new product has the same characteristics as the predicate, or if different characteristics from the predicate, information that shows that the new product does not raise different questions of public health (section 910 of the FD&C Act). For example, for a change to FSC paper after February 15, 2007, you may not need to include information about aflatoxin B1 in your 905(j) report because that information may not be

appropriate to demonstrate substantial equivalence of the new product to the predicate product.

If you have additional questions regarding HPHC that should be reported in your submission of 905(j) reports, and would like to discuss your questions with the agency, please contact CTP to request a meeting in accordance with 21 C.F.R. 10.65.

18. Question:
Do I need to submit an environmental assessment as part of my section 905(j) report?

Response:

Yes. FDA's regulations implementing the National Environmental Policy Act (NEPA) of 1969 require that "[a]ll applications or petitions requesting agency action require the submission of an [environmental assessment] or a claim of categorical exclusion." 21 CFR 25.15(a). There are no categorical exclusions in place for tobacco products; therefore, manufacturers submitting applications or reports for any of the three regulatory pathways to legally market a new tobacco product (including reports under section 905(j)) must include environmental assessments as part of their submissions. You should refer to 21 CFR Part 25 for additional information. If you have questions regarding what you should include in your environmental assessment, and would like to discuss your questions with the agency, please contact CTP to request a meeting in accordance with 21 C.F.R. 10.65.